# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appl. No. : 10/066,436

Applicants : Steve G. Baker, et al.

Filed : January 30, 2002

Title : THORACIC GRAFT AND DELIVERY SYSTEM

Art Unit : 3738

Examiner : Thomas C. Barrett

Confirmation No. 5619

Docket No.: : ENDOV-59271

Customer No. : 24201

Date : March 12, 2007

#### REPLY TO EXAMINER'S ANSWER

MS: Appeal Brief Patents Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

This Reply Brief is being filed in response to the Examiner's Answer dated January 12,

2007. Please charge any fee due in connection with the filing of this paper to our Deposit

Account No. 06-2425.

#### I. <u>STATUS OF CLAIMS</u>

The status of the claims in this application are:

## A. Total Number of Claims in the Application

The claims in the application are: Claims 22-32

## B. Status of All of the Claims

Each of pending claims 22-32 stand as finally rejected under 35 U.S.C. § 103(a).

## C. <u>Claims on Appeals</u>

The claims on appeal are each of pending claims 22-32.

# II. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 22-32 were improperly rejected under 35 U.S.C. § 103(a) as being unpatentable over Rhodes in view of Lazarus et al.

#### III. ARGUMENT

In the Examiner's Answer dated January 12, 2007, the Examiner maintained the rejection of claims 22-32 under 35 U.S.C. § 103(a) as being unpatentable over Rhodes (5,122,154) in view of Lazarus et al. (5,275,622). In maintaining the rejection of the claims, the Examiner stated that the motivation to modify the teachings of the Rhodes patent in view of Lazarus et al. is "to yieldably urge the graft from a compressed position to a second expanded condition" as found in Lazarus et al. (col. 8, lines 44-49). The Examiner then stated that it is therefore more than just "The level of ordinary skill in the art that is relied upon for motivation" and that "While Rhodes does teach a stent formed from rigid links or struts this does not teach away from the rigid links or struts comprising self-expanding frame."

It is respectfully submitted, however, that the Rhodes patent does indeed teach away from a stent comprising a self-expanding frame. Significantly, in the Background Of The Invention of the Rhodes patent, the invention of Rhodes is described as relating "generally to medical devices and methods of use in vessels, ducts or lumens of living beings, and more particularly to expandable intraluminal grafts and methods of use within the vascular tree of a living being to revascularize any blood vessel which is occluded (either partially or totally) by intrinsic or extrinsic disease" (Col. 1, lines 5-12). The Background Of The Invention of the Rhodes patent then provides a background concerning intraluminal endovascular grafting and specifically states that "The stent devices which have been used for the foregoing procedures have included cylindrical springs of stainless steel, sleeves of expandable heat sensitive material, and expandable sleeves formed of linked stainless steel wires arranged in a zig-zag configuration. The problems with these devices is that there is no effective control over the final expanded configuration of each structure" (Col. 2, lines 31-38). The Rhodes patent later states that

"Therefore, there is an element of significant risk in the use of the prior art stent devices for revascularization of occluded arteries" (Col. 2, lines 60-62) and thus concludes that "the need exists for an expandable intraluminal vascular bypass graft and methods of use which can overcome the disadvantages of the prior art" (col. 3, lines 46-49). Accordingly, in the Summary of The Invention, the Rhodes stent is described as embodying structure which requires a balloon catheter to convert from a contracted state to an expanded state, and once expanded "the stent is resistant to contraction back to the compact state."

Therefore, it is respectfully submitted that the Rhodes patent clearly teaches away from self-expanding structure.

Referring again to the Examiner's Answer, it is noted that the Examiner has taken the position that the combination of Lazarus and Rhodes would overcome "disadvantages of the prior art" cited in the Rhodes patent. It is respectfully submitted, however, that even if the combined teachings of Rhodes and Lazarus did indeed address certain disadvantages of the prior art identified by the Rhodes patent, since Rhodes teaches away from using self-expanding structures such as that taught by Lazarus, one of ordinary skill in the art would not have modified the approach taught by Rhodes to include the self-expanding structure taught by Lazarus.

Similarly, the Appellants believe that the Examiner's argument in the Answer concerning changing the principal operation of the teachings of the Rhodes reference is misplaced. In that connection, the Examiner stated that "a self-expanding stent can still be expanded with a balloon and the device would still function as an endovascular bypass graft without substantial reconstruction or redesign of the elements shown." However, employing a balloon to facilitate deployment of a self-expanding stent simply does not address the words of caution set forth in the Rhodes patent concerning having "no effective control over the final expanded

configuration" of a self-expanding structure. In fact, as in the <u>In re Ratti</u> case, it is submitted modifying Rhodes to include self-expanding structure would require a substantial reconstruction and redesign of elements shown in the Rhodes reference as well as change the basic principal under which the device disclosed in the Rhodes reference was designed to operate, since the non-self-expanding structure of Rhodes would be replaced by self-expanding structure, the very structure Rhodes seeks to avoid, in order to meet the limitations recited in independent claim 22 and its dependent claims.

Therefore, it is again respectfully submitted that there is no motivation or suggestion to combine the Rhodes and Lazarus references in the manner suggested by the Examiner. Further, there is a lack of an objective reason for the combination and the Examiner has proffered an impermissible change of principal operation of the Rhodes device. Thus, it is respectfully submitted that the combination of Rhodes and Lazarus et al. does not constitute a *prima facia* case of obviousness which would be necessary to properly reject claims 22-32.

#### **CONCLUSION**

For all the reasons stated above, Applicant respectfully submits that the Examiner has erred in rejecting claims 22-32. It is respectfully requested that the Board reverse the rejection of claims 22-32 and allow claims 22-32 to issue.

Respectfully submitted,

FULWIDER PATTON LLP

By: /John V. Hanley/ John V. Hanley Registration No. 38,171

JVH/kst 6060 Center Drive, Tenth Floor Los Angeles, CA 90045 Telephone: (310) 824-5555 Facsimile: (310) 824-9696

Customer No. 24201

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